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FILED IN THE  
U.S. DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON

4 Jul 08, 2025  
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7 SEAN F. MCAVOY, CLERK

8 UNITED STATES DISTRICT COURT  
9 EASTERN DISTRICT OF WASHINGTON  
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12 STATE OF WASHINGTON, STATE  
13 OF OREGON, STATE OF ARIZONA,  
14 STATE OF COLORADO, STATE OF  
15 CONNECTICUT, STATE OF  
16 DELAWARE, STATE OF ILLINOIS,  
17 ATTORNEY GENERAL OF  
18 MICHIGAN, STATE OF NEVADA,  
19 STATE OF NEW MEXICO, STATE  
20 OF RHODE ISLAND, STATE OF  
VERMONT, DISTRICT OF  
COLUMBIA, STATE OF HAWAII,  
STATE OF MAINE, STATE OF  
MARYLAND, STATE OF  
MINNESOTA, and  
COMMONWEALTH OF  
PENNSYVLANIA,

16 Plaintiffs,  
17  
18 v.  
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UNITED STATES FOOD AND  
DRUG ADMINISTRATION,  
ROBERT M. CALIFF, in his official  
capacity as Commissioner of Food and  
Drugs, UNITED STATES

NO. 1:23-CV-3026-TOR

ORDER ON MOTIONS FOR  
SUMMARY JUDGMENT

1 DEPARTMENT OF HEALTH AND  
2 HUMAN SERVICES, and XAVIER  
3 BECERRA, in his official capacity as  
Secretary of the Department of Health  
and Human Services,

4 Defendants.

5 BEFORE THE COURT are Plaintiffs' Motion for Summary Judgment (ECF  
6 No. 156) and Defendants' Cross-Motion for Summary Judgment (ECF No. 171).

7 The Court has determined that oral argument is unnecessary. The Court has fully  
8 reviewed the record and files herein and is fully informed. For the reasons  
9 discussed below, Defendants' Cross-Motion for Summary Judgment (ECF No.  
10 171) is **granted**.

11 **BACKGROUND**

12 This case concerns federal regulation of mifepristone used in connection  
13 with the termination of early pregnancy. ECF No. 35. Plaintiffs seek a remand to  
14 the FDA. The following facts are generally undisputed for purposes of resolving  
15 the instant motion.

16 In 1992, Subpart H regulations authorized the Food and Drug  
17 Administration ("FDA") to require conditions "needed to assure safe use" for  
18 certain drugs. Final Rule, 57 Fed. Reg. 58,942, 58,958 (December 11, 1992)  
19 (codified at 21 C.F.R. § 314.520). In September 2000, FDA approved

1 mifepristone<sup>1</sup> under Subpart H, concluding that mifepristone is safe and effective  
2 for medical termination of intrauterine pregnancy through 49 days' gestation when  
3 used in a regimen with the already-approved drug, misoprostol. ECF No. 35 at 21,  
4 ¶ 85. FDA's restrictions on mifepristone included requiring (1) an in-person  
5 dispensing requirement where the drug could only be dispensed in a hospital,  
6 clinic, or medical office, by or under the supervision of a certified provider who at  
7 the time could only be a physician, (2) providers attest to their clinical abilities in a  
8 signed form kept on file by the manufacturer, and agree to comply with reporting  
9 and other REMS requirements, and (3) prescribers and patients review and sign a  
10 form with information about the regimen and risks and that the prescriber provide  
11 copies to the patient and patient's medical record. *Id.* at 24, ¶ 87.

12 From 1992 to February 2002, seven New Drug Applications ("NDA"),  
13 including Mifeprex, were approved subject to these conditions, in contrast to the  
14 961 NDAs with no additional restrictions from January 1993 to September 2005.  
15 ECF No. 35 at 24–25, ¶ 88.

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17  
18 As referenced herein, mifepristone is the drug used for early termination of  
19 pregnancy, such as Mifeprex and the generic drug. This Order does not impact  
20 mifepristone as used in Korlym, a drug used to treat Cushing's syndrome.

1 The Food and Drug Administration Amendments Act of 2007 effectively  
2 replaced Subpart H with the REMS statute codified at 21 U.S.C. § 355-1. Pub. L.  
3 No. 110-85, tit. IX, § 901. All drugs previously approved under Subpart H,  
4 including Mifeprex, were deemed to have a REMS in place. Pub. L. No. 110-85,  
5 tit. IX, § 909(b). Under the Federal Food, Drug and Cosmetic Act (“FDCA”), a  
6 new drug cannot be marketed and prescribed until it undergoes a rigorous approval  
7 process to determine that it is safe and effective. 21 U.S.C. § 355.

8 In 2011, FDA issued a new REMS for Mifeprex incorporating the same  
9 restrictions under which the drug was approved eleven years earlier. *Id.*, ¶ 90; ECF  
10 No. 51-2. In 2013, FDA reviewed the existing REMS and reaffirmed the  
11 restrictions in place. ECF No. 35 at 25, ¶ 91.

12 In 2015, Mifeprex’s manufacturer submitted a supplemental NDA proposing  
13 to update the label to reflect evidence-based practices across the country – namely,  
14 the use of 200 mg of mifepristone instead of 600 mg. *Id.*, ¶ 92. In July 2015, the  
15 manufacturer submitted its REMS assessment, proposing minor modifications. *Id.*  
16 This submission prompted a review of the Mifeprex label and REMS by FDA. *Id.*  
17 at 26, ¶ 93. As part of the review, FDA received letters from more than 40 medical  
18 experts, researchers, advocacy groups, and professional associations who asked,  
19 *inter alia*, that the REMS be eliminated in their entirety. *Id.* One letter asked FDA  
20

1 to “[e]liminate the REMS and ETASU (Elements to Assure Safe Use), including  
2 eliminating the certification and patient agreement requirements. *Id.* at 27, ¶ 95.

3 In 2016, FDA found “no new safety concerns have arisen in recent years,  
4 and that the known serious risks occur rarely,” and that “[g]iven that the number of  
5 … adverse events appear to be stable or decreased over time, it is likely that …  
6 serious adverse events will remain acceptably low.” *Id.* at 30, ¶ 100. Following  
7 this review, FDA changed Mifeprex’s indication, labeling, and REMS, including  
8 increasing the gestational age limit from 49 to 70 days, reducing the number of  
9 required in-person clinic visits to one, finding at-home administration of  
10 misoprostol safe, finding no significant differences in outcomes based on whether  
11 patients had a follow-up phone call or in person or based on the timing of those  
12 appointments, and allowing a broader set of healthcare providers to prescribe  
13 mifepristone. *Id.*, ¶ 101. However, FDA still required that mifepristone be  
14 administered in a clinic setting. *Id.*

15 In 2019, FDA approved a different manufacturer’s abbreviated NDA for a  
16 generic version of mifepristone and established the Mifepristone REMS Program,  
17 which covered both Mifeprex and the generic drug. *Id.* at 32, ¶ 103; ECF No. 51-  
18 3. In May 2020, American College of Obstetricians and Gynecologists (“ACOG”)  
19 sued FDA, challenging the Mifepristone REMS Program’s in-person dispensing  
20 requirement in light of the COVID-19 pandemic. ECF No. 35, ¶ 104. In that

1 case, the district court temporarily enjoined FDA from enforcing the in-person  
2 dispensation requirements under the REMS in light of the COVID-19 pandemic.

3 *American College of Obstetricians and Gynecologists v. United States Food and*  
4 *Drug Administration*, 472 F. Supp. 3d 183 (D. Md. 2020).

5 In April 2021, FDA suspended the in-person dispensing requirement during  
6 the COVID-19 public health emergency because, during the six-month period in  
7 which the in-person dispensing requirement had been enjoined, the availability of  
8 mifepristone by mail showed no increases in serious patient safety concerns. *Id.*, ¶  
9 105.

10 On May 7, 2021, FDA announced it would review whether the Mifepristone  
11 REMS Program should be modified. ECF No. 51-4. FDA reviewed materials  
12 between March 29, 2016 and July 26, 2021, as well as publications found on  
13 PubMed and Embase and those provided by “advocacy groups, individuals,  
14 plaintiffs in *Chelius v. Becerra*, 1:17-493-JAO-RT (D. Haw.), application holders,  
15 and healthcare providers and researchers. *Id.* at 10–11.

16 On December 16, 2021, FDA announced its conclusions regarding the  
17 Mifepristone REMS Program. ECF No. 51-5. On January 3, 2023, FDA accepted  
18 these conclusions by approving the supplemental applications proposing  
19 conforming modifications. ECF Nos. 51-8; 51-11. The 2023 REMS removed the  
20 in-person dispensing requirement and added a pharmacy-certification requirement.

1 ECF Nos. 51-4, 51-5. The FDA maintained the Prescriber and Patient Agreement  
2 Form requirements. *Id.*

3 **DISCUSSION**

4 The Court may grant summary judgment in favor of a moving party who  
5 demonstrates “that there is no genuine dispute as to any material fact and that the  
6 movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). In ruling  
7 on a motion for summary judgment, the court must only consider admissible  
8 evidence. *Orr v. Bank of America, NT & SA*, 285 F.3d 764, 773 (9th Cir. 2002).  
9 The party moving for summary judgment bears the initial burden of showing the  
10 absence of any genuine issues of material fact. *Celotex Corp. v. Catrett*, 477 U.S.  
11 317, 323 (1986). The burden then shifts to the non-moving party to identify  
12 specific facts showing there is a genuine issue of material fact. *See Anderson v.*  
13 *Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). “The mere existence of a scintilla  
14 of evidence in support of the plaintiff’s position will be insufficient; there must be  
15 evidence on which the jury could reasonably find for the plaintiff.” *Id.* at 252.

16 Under the APA, a court shall “hold unlawful and set aside agency action,  
17 findings, and conclusions found to be … arbitrary [and] capricious … or otherwise  
18 not in accordance with law [or] in excess of statutory … authority, or limitations.”  
19 5 U.S.C. § 706(2)(A), (C). Courts must uphold an agency action unless it (1)  
20 “relied on factors which Congress has not intended it to consider,” (2) “entirely

1 failed to consider an important aspect of the problem,” (3) “offered an explanation  
2 for its decision that runs counter to the evidence before the agency,” or (4) the  
3 “decision is so implausible that it could not be ascribed to a difference in view or  
4 the product of agency expertise.” *Turtle Island Restoration Network v. U.S. Dep’t  
of Commerce*, 878 F.3d 725, 732–33 (9th Cir. 2017) (internal quotation marks  
5 omitted). Additionally, a decision is arbitrary and capricious if it is internally  
6 inconsistent with the underlying analysis. *Nat’l Parks Conservation Ass’n v. EPA*,  
7 788 F.3d 1134, 1141 (9th Cir. 2015). Review is “at its most deferential” regarding  
9 an agency’s scientific determinations within its area of expertise. *Baltimore Gas &  
Elec., Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1982).

11       Regulations are valid if they are “consistent with the statute under which  
12 they are promulgated.” *United States v. Larionoff*, 431 U.S. 864, 873 (1977).  
13 Under the FDCA, a new drug cannot be marketed and prescribed until it undergoes  
14 a rigorous approval process to determine that it is safe and effective. 21 U.S.C.  
15 § 355. For certain drugs, a risk evaluation and mitigation strategy (REMS) is  
16 required when the agency determines, after considering six factors, it is “necessary  
17 to ensure that the benefits of the drug outweigh the risks of the drug.” 21 U.S.C.  
18 § 355-1(a)(1). An existing REMS may be modified or removed to “ensure the  
19 benefits of the drug outweighs the risks of the drug [or] minimize the burden on the  
20

1 health care delivery system of complying with the strategy.” 21 U.S.C. § 355-  
2 1(g)(4)(B).

3 Moreover, a REMS may include elements that are necessary to assure safe  
4 use [ETASU] due to a drug’s “inherent toxicity or potential harmfulness” if the  
5 drug has “been shown to be effective, but is associated with a serious adverse drug  
6 experience, can be approved only if, or would be withdrawn unless, such elements  
7 are required as part of such strategy to mitigate a specific serious risk listed in the  
8 labeling of the drug.” 21 U.S.C. § 355-1(f)(1)(A). A “serious adverse drug  
9 experience” is one that results in:

10 death; an adverse drug experience that places the patient at immediate  
11 risk of death...; inpatient hospitalization or prolongation of existing  
12 hospitalization; a persistent or significant incapacity or substantial  
13 disruption of the ability to conduct normal life functions; or a  
congenital anomaly or birth defect; or based on appropriate medical  
judgment, may jeopardize the patient and may require a medical or  
surgical intervention to prevent [such] an outcome.

14 21 U.S.C. § 355-1(b)(4)(A). If the FDA determines ETASU is required, the  
15 ETASU shall:

16 not be unduly burdensome on patient access to the drug, considering  
17 in particular – patients with serious or life-threatening diseases or  
18 conditions; patient who have difficulty accessing health care (such as  
patients in rural or medically underserved areas); and patients with  
functional limitations; and to the extent practicable, so as to minimize  
the burden on the health care delivery system – conform with  
19 [ETASU] for other drugs with similar, serious risks; and be designed  
20 to be compatible with established distribution, procurement, and  
dispensing systems from drugs.

1 21 U.S.C. § 355-1(f)(2)(C)–(D).

2 Now that the Court has a full record, it is not the Court’s role to review the  
3 scientific evidence and decide whether mifepristone’s benefits outweigh its risks  
4 without REMS and/or ETASU. That is precisely FDA’s role. However, based on  
5 the present record, FDA did assess whether mifepristone qualifies for REMS and  
6 ETASU based on the criteria set forth under 21 U.S.C. § 355-1(g)(4)(B). Even  
7 under a deferential review, it appears FDA fully considered the important aspect of  
8 the issues in this case and came to a reasonable conclusion.

9 The Court cannot find, based on the full record before it, that the FDA was  
10 arbitrary and capricious in its decision. The FDA did not ignore the laws that  
11 apply nor the regulations. The FDA reviewed materials between March 29, 2016  
12 and July 26, 2021, not the subsequent Canadian study.

13 Defendants argue Plaintiffs lack standing, have not exhausted their  
14 administrative claims, and cannot assert Constitutional claims. Given this Court’s  
15 disposition of the case, these issues are now moot.

16 **ACCORDINGLY, IT IS HEREBY ORDERED:**

17 1. The Preliminary Injunction (ECF No. 80) is **VACATED**.  
18 2. Defendants’ Cross-Motion for Summary Judgment (ECF No. 171) is  
19 **GRANTED**.  
20 3. Plaintiffs’ Motion for Summary Judgment (ECF No. 156) is **DENIED**.

1 The District Court Executive is directed to enter this Order and Judgment  
2 accordingly, and furnish copies to counsel, and **CLOSE** the file.

3 DATED July 8, 2025.



A handwritten signature in blue ink that reads "Thomas O. Rice".

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5 THOMAS O. RICE  
6 United States District Judge  
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